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10/797,159	03/10/2004	Michael E. Goodwin	11398.64.1	4068

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WORKMAN NYDEGGER
(F/K/A WORKMAN NYDEGGER & SEELEY)
60 EAST SOUTH TEMPLE
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EXAMINER	
COOLEY, CHARLES E	
ART UNIT	**PAPER NUMBER**
1723	

DATE MAILED: 12/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/797,159	GOODWIN ET AL.	
	Examiner	Art Unit	
	Charles E. Cooley	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7-16,21-24,28-30,32-34,36,37 and 39-42* is/are rejected.

7)☒ Claim(s) *5,6,17-20,25-27,31,35,38 and 43* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

NON-FINAL OFFICE ACTION

1. This application has been assigned to Technology Center 1700, Art Unit 1723 and the following will apply for this application:

Please direct all written correspondence with the correct application serial number for this application to Art Unit 1723.

Telephone inquiries regarding this application should be directed to the Electronic Business Center (EBC) at http://www.uspto.gov/ebc/index.html or 1-866-217-9197 or to the Examiner at (571) 272-1139. All official facsimiles should be transmitted to the centralized fax receiving number 571-273-8300.

Priority

2. Acknowledgment is made of applicant's claim for domestic priority under 35 U.S.C. § 119(e).

Information Disclosure Statement

3. Note the attached PTO-1449 forms submitted with the Information Disclosure Statements filed 16 AUG 2004, 27 JAN 2005, and 9 MAR 2005.

Drawings

4. The drawings are objected to because the "hole" referenced in [0041] should be labeled in the appropriate Figure(s).

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application.

5. Applicant should verify that (1) all reference characters in the drawings are described in the detailed description portion of the specification and (2) all reference characters mentioned in the specification are included in the appropriate drawing Figure(s) as required by 37 CFR 1.84(p)(5).

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

Replacement Drawing Sheets

Drawing changes must be made by presenting replacement figures which incorporate the desired changes and which comply with 37 CFR 1.84. An explanation of the changes made must be presented either in the drawing amendments, or remarks, section of the amendment. Any replacement drawing sheet must be identified in the top margin as "Replacement Sheet" (37 CFR 1.121(d)) and include all of the figures appearing on the immediate prior version of the sheet, even though only one figure may be amended. The figure or figure number of the amended drawing(s) must not be labeled as "amended." If the changes to the drawing figure(s) are not accepted by the examiner, applicant will be notified of any required corrective action in the next Office action. No further drawing submission will be required, unless applicant is notified.

Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin.

Annotated Drawing Sheets

A marked-up copy of any amended drawing figure, including annotations indicating the changes made, may be submitted or required by the examiner. The annotated drawing sheets must be clearly labeled as "Annotated Marked-up Drawings" and accompany the replacement sheets.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDONMENT of the application.

If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability.

Specification

6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

7. The disclosure is objected to because of the following informalities:

a. the specification is objected to under 37 CFR 1.73 and MPEP 608.01(d) as lacking a summary of the invention.

§ 1.73 Summary of the invention.

A brief summary of the invention indicating its nature and substance, which may include a statement of the object of the invention, should precede the detailed description. Such summary should, when set forth, be commensurate with the invention as claimed and any object recited should be that of the invention as claimed.

Appropriate correction is required.

8. The abstract is acceptable.

9. The title is acceptable.

10. The use of the apparent trademark "Maxistirrer" in [0026] has been noted in this application. Trademarks should be capitalized wherever they appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be

respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1, 2, 4, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 22, 24, 28, 29, 30, 32, 33, 34, 36, 37, 39, 40, and 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Terentiev (US 2005/0002274 A1).

Terentierv '274 discloses, as noted in the underlined text below and the attached Figures, a method and a mixing bag assembly comprising a body 10 bounding a compartment, the body being comprised of a flexible sheet; a mixing dish 14 or 30 secured/sealed to the body (Figs. 3A, 3B, 6A, 6B), the mixing dish having a floor in communication with the compartment of the body; a magnetic stir bar 18 disposed on the floor of the mixing dish; wherein the body comprises a two-dimensional pillow style bag or a three dimensional bag (Figs. 1, 2, 3A, 3B, 6A, 6B); the mixing dish further comprises an annular side wall 30 or 34 upstanding from the floor, the side wall terminating at a perimeter edge, the perimeter edge being secured to the body 10; the mixing dish 14 or 30 is more rigid than the body; the mixing dish 14 or 30 is substantially

rigid; wherein the mixing dish 14 or 30 comprises a substantially flat plate 22 secured to the body 10; further comprising at least one fluid port mounted on the body so as to communicate with the compartment of the body; wherein the compartment of the body 10 has a volume of at least 50 liters [para. 0007]; a substantially rigid container C (Fig. 2) having a floor and an upper side wall upstanding therefrom, the upper side wall and floor bounding a first chamber; a magnetic mixer 24 disposed below the floor of the container; and the mixing bag assembly 10 at least partially disposed within the first chamber of the container C, the mixing bag assembly 10 comprising a collapsible body 10 bounding a compartment, the body having a first end and an opposing second end, at least a portion of the second end of the body resting on or adjacent to the floor of the container (Fig. 2); a mixing dish 14 or 30 being more rigid than the collapsible body, the mixing dish being secured at the second end of the collapsible body; and the magnetic stir bar 18 disposed on the mixing dish; wherein the floor is integrally formed with the upper side wall of the container C (Fig. 2); wherein at least a portion of the mixing dish 14 or 30 is resting on the floor of the container C; wherein the floor has an opening 24b extending therethrough, at least a portion of the mixing dish extending through the opening on the floor; wherein mixing dish 14 or 30 is disposed directly on or adjacent to the magnetic mixer 24; wherein the mixing dish 14 or 30 has an interior surface and an opposing exterior surface, at least a portion of the interior surface being in communication with the compartment of the body, at least a portion of the exterior surface not being in communication with the compartment of the body; the mixing dish 14 or 30 having at least one sized opening (defined by the diameter of annular side wall

30 or 34) so as to provide fluid communication between the cavity of the mixing dish assembly and the compartment of the body; the mixing dish 14 or 30 having floor and a side wall with a retention plate 22 mounted to the side wall (claim 41).

More specifically and with regard to the claimed method, Terentierv '274 discloses a vessel intended for receiving a fluid and a fluid-agitating element. The vessel comprises a bag capable of receiving and holding the fluid. The bag includes a rigid portion having a first receiver for receiving and holding the fluid-agitating element at a home location when positioned in the vessel.

In one embodiment, the first receiver is a first inwardly-projecting post for positioning in an opening or recess in the fluid-agitating element. The first post may include an oversized portion for capturing the fluid-agitating element. The oversized portion is preferably the head of the first post and is T-shaped, cross-shaped, Y-shaped, L-shaped, spherical, cubic, or otherwise formed having a shape that confines the fluid-agitating element to adjacent the post.

The bag may further include a second receiver projecting outwardly from the bag. The second receiver facilitates aligning the fluid-agitating element with an external structure, such as a motive device for levitating or rotating the fluid-agitating element. In one particularly preferred embodiment, the first receiver is a first, inwardly-projecting post and the second receiver is a second, outwardly-projecting post coaxial with the first inwardly-projecting post.

The first receiver may include a peripheral flange mating with a portion of the bag to create an interface along which a seal is formed. Instead of comprising a post, the

first receiver may be cap-shaped and include a cavity facing the interior of the bag. Still another option is for the first receiver to include an generally upstanding peripheral sidewall over which the fluid-agitating element is received and a cavity adapted for receiving a portion of an external structure for rotating the fluid-agitating element. The first receiver may also include a bearing for directly engaging and supporting the fluid-agitating element in a non-levitating fashion.

In accordance with a second aspect of the invention, a vessel intended for use in receiving a fluid and a fluid-agitating element, such as a magnetic impeller, positioned adjacent to an external structure, such as a housing of a motive device for levitating and/or rotating the fluid-agitating element, is disclosed. The vessel comprises a bag capable of receiving and holding the fluid. The bag includes a first inwardly-projecting post for receiving and holding the fluid-agitating element at a home location when positioned in the bag and a receiver adapted for receiving at least a portion of the external structure and aligning the fluid-agitating element relative thereto.

In one embodiment, the body comprises a flexible portion and a rigid portion in which the first post and the receiver are formed. The receiver may take the form of a second outwardly projecting post, with the first and second posts being coaxial. Alternatively, the receiver may be defined by a rigid, cap-shaped portion having a cavity and a peripheral flange connected to the flexible portion, with the cavity facing an interior of the body for receiving the fluid-agitating element when positioned therein. The first inwardly directed post may be positioned at least partially in the cavity of the receiver or may include a bearing for directly supporting the fluid-agitating element.

In accordance with a third aspect of the invention, the combination of a vessel and a fluid-agitating element is disclosed. The vessel comprises a flexible portion and a rigid portion including a receiver for receiving and holding a fluid-agitating element at a home location or expected position within the vessel. The combination may further include a motive device for at least rotating the fluid-agitating element in the vessel. The fluid-agitating element used in the combination may be at least partially magnetic and may also include at least one blade or vane. The vessel may be at least initially hermetically sealed with the fluid-agitating element positioned therein.

In accordance with a fourth aspect of the invention, the combination of a vessel and a fluid-agitating element is disclosed, with the vessel comprising a first receiver for receiving the fluid-agitating element. The first receiver includes an oversized portion for capturing the fluid-agitating element on the receiver, but the fluid-agitating element is free of direct attachment to the receiver. The vessel may further include a second receiver for receiving a portion of an external structure to assist in aligning the fluid-agitating element relative thereto. The first receiver is preferably a post and the oversized portion is a head end of the post that is T-shaped.

In accordance with a fifth aspect of the invention, a vessel for receiving a fluid and a fluid-agitating element, such as an impeller, is disclosed. The vessel comprises a bag capable of receiving and holding the fluid and a rigid receiver connected to the bag. The receiver receives and holds the fluid-agitating element at a home location when positioned in the bag.

In one embodiment, the rigid receiver is cap-shaped and includes a peripheral flange connected to the bag to form a seal. Alternatively, the rigid receiver is positioned in contact with an interior surface of the bag. Still another alternative is to position the rigid receiver in contact with an exterior surface of the bag.

In accordance with a sixth aspect of the invention, a system for agitating a fluid is disclosed. The system comprises a fluid-agitating element and a vessel for receiving the fluid, the vessel including a flexible portion and a rigid portion. The rigid portion includes a receiver for receiving and holding the fluid-agitating element at a home location in the vessel. A motive device for at least rotating the fluid-agitating element may also form part of the system.

In one embodiment, the motive device also levitates the fluid-agitating element in the vessel. The fluid-agitating element is at least partially magnetic or ferromagnetic and the motive device includes a rotating drive magnet structure for forming a magnetic coupling with the fluid-agitating element, an electromagnetic structure for rotating and levitating the fluid-agitating element, or a superconducting element for both levitating and rotating the fluid-agitating element.

In accordance with a seventh aspect of the invention, a method of positioning a fluid-agitating element in a bag intended for receiving a fluid in need of agitation is disclosed. The method comprises the step of providing the bag with a rigid portion including a receiver for receiving and holding the fluid-agitating element at a home location when positioned in the bag. Preferably, the receiver includes a post projecting

toward an interior of the bag, the fluid-agitating element includes an opening, and the providing step comprises inserting the post through the opening. Alternatively, the receiver may include a peripheral sidewall and a cavity facing an interior of the bag, in which case the providing step comprises positioning the fluid-agitating element in the cavity. Still another alternative is for the receiver to include a peripheral sidewall and a cavity facing an exterior of the bag, in which case the fluid agitating element includes an opening or recess and the providing step comprises positioning the peripheral sidewall of the receiver in the opening or recess.

In accordance with a seventh aspect of the invention, a method of agitating a fluid is disclosed. The method comprises providing a bag with a receiver for receiving and holding a fluid-agitating element at a home location within the bag, placing a fluid in the bag, and rotating the fluid-agitating element. In one embodiment, the bag comprises a flexible portion and a rigid portion including the receiver, and the providing step includes connecting the rigid portion to the flexible portion. The step of placing a fluid in the bag is completed after the fluid-agitating element is received in the receiver. The fluid-agitating element may be at least partially magnetic or ferromagnetic, and the step of rotating may include forming a non-contact coupling with a motive device external to the bag. The providing step may include providing a bearing on the receiver for directly engaging and supporting the fluid-agitating element. The method may further include the steps of folding the bag for storage or shipping with the fluid-agitating element in the receiver and unfolding the bag before the placing step, or hermetically sealing the bag

after the providing step. The placing step may also comprise introducing the fluid through a sterile fitting provided in the bag.

FIG. 1 discloses one embodiment of the vessel of the present invention in the form of a bag 10. In this embodiment, the bag 10 includes a body having a flexible or non-rigid portion 12, which is illustrated schematically, and a rigid or stiff portion 14, which is shown in cross-section. However, as outlined further in the description that follows, the use of the many of the present inventive concepts disclosed herein with vessels that are completely rigid is also possible.

The bag 10 may be hermetically sealed and may have one or more openings or fittings (not shown) for introducing or recovering a fluid. Alternatively, the bag 10 may be unsealed or open-ended. The particular geometry of the bag 10 employed normally depends on the application and is not considered critical to the invention. For example, in the case of a sterile fluid, a hermetically sealed, pre-sterilized bag with an aseptic fitting might be desirable; whereas, in the case where sterility is not important, an open-ended or unsealed bag might be suitable. The main important point is that the bag 10 is capable of receiving and at least temporarily holding a fluid (which is used herein to denote any substance capable of flowing, as may include liquids, liquid suspensions, gases, gaseous suspensions, or the like, without limitation).

The rigid portion 14 includes a first receiver 16 for receiving and holding a fluid-agitating element 18 at a home location (or expected position), when positioned in the bag 10. It is noted that "holding" as used herein defines both the case where the fluid-agitating element 18 is directly held and supported by the first receiver 16 (see below)

against any significant side-to-side movement (save tolerances), as well as where the first receiver 16 merely limits the fluid-agitating element to a certain degree of side-to-side movement within the bag 10. In this embodiment, an opening 18a is provided in the fluid-agitating element 18 and the first receiver 16 is a post 20 projecting toward the interior of the bag 10 (see FIGS. 1a and 1b). The post 20 is sized for receiving the fluid-agitating element 18 by extending through the opening 18a formed in the body 18b thereof (which is depicted as being annular, but not necessarily circular in cross-section). As illustrated in FIG. 1, it is preferable that the size of the opening 18a is such that the fluid-agitating element 18 may freely rotate and move in the axial direction along the post 20 without contacting the outer surface thereof. Despite this freedom of movement, the post 20 serving as the first receiver 16 is still considered to hold, confine, or keep the fluid-agitating element 18 at a home location or expected position within the vessel 20 by contacting the surface adjacent to the opening 18a as a result of any side-to-side movement (the boundaries of which are defined by the dimensions of the opening).

The flexible portion 12 of the bag 10 may be made of thin (e.g., having a thickness of between 0.1 and 0.2 millimeters) polyethylene film. The film is preferably clear or translucent, although the use of opaque or colored films is also possible. The rigid portion 14 including the post 20 may be formed of plastic materials, such as high density polyethylene (HDPE), ultrahigh molecular weight (UHMW) polyethylene, or like materials. Of course, these materials do have some inherent flexibility when used to form relatively thin components or when a moderate amount of bending force is applied

thereto. Despite this flexibility, the rigid portion 14 is distinguished from the flexible portion 12, in that it generally maintains its shape under the weight of any fluid introduced in the bag 10.

Optionally, the post 20 may include a portion 20a for capturing the fluid-agitating element 18 and assisting in holding it thereon. The portion 20a is preferably oversized and forms the head or end of the post 20. By "oversized," it is meant that at least one dimension (length, width, diameter) of this portion 20a of the post 20 is greater than the corresponding dimension of the opening 18a in the fluid-agitating element 18. For example, the portion 20a is shown in FIG. 1 as being disc-shaped, such that it provides the head end of the post 20 with a generally T-shaped cross section. To prevent interference with the levitation and rotation of the fluid-agitating element 18, the oversized portion 20a is strategically positioned at a certain distance along the post 20. In the case where it is oversized, the post 20 may be removably attached to the rigid portion 14 through the opening 18a in the fluid-agitating element 18 (such as by providing a threaded bore in the rigid portion for receiving a threaded end of the post, or as shown in FIG. 1c, a bore 14a having a groove 14b for establishing a snap-fit engagement with a corresponding projection 20b on a tapered end portion 20c of the post). In the case where the post 20 is unitarily formed with the rigid portion 14 and includes an oversized head portion 20a, this portion should be sufficiently thin such that it flexes or temporarily deforms to allow the fluid-agitating element 18 to pass initially (see FIG. 1b and note action arrow A, which demonstrates the direction of force for deforming the oversized head 20a such that it passes through the opening 18a).

Alternatively, this portion 20a of the post 20 need not be oversized, as defined above, but instead may simply be sufficiently close in size to that of the opening 18a such that the fluid-agitating element 18 must be precisely aligned and register with the post 20 in order to be received or removed. In any case, it is again important to note that the fluid-agitating element 18 is held in place in the vicinity of the post 20, but remains free of direct attachment. In other words, while the first receiver 16 (post 20) confines or holds the fluid-agitating element 18 at a home location or expected position within the bag 10, it is still free to move side-to-side to some degree (which in this case is defined by the size of the opening 18a), and to move along the first receiver 16 in the axial direction (vertical, in the embodiment shown in FIG. 1), as is necessary for levitation.

As perhaps best shown in FIG. 1a, the rigid portion 14 in this embodiment further includes a substantially planar peripheral flange 22. The flange 22 may be any shape or size, and is preferably attached or connected directly to the bag 10 at the interface I between the two structures (which may be created by overlapping the material forming the flexible portion 12 of the bag on an inside or outside surface of the flange 22 to form an overlapping joint, or possibly in some cases by forming a butt joint). In the case where the bag 10 and flange 22 are fabricated of compatible plastic materials, the connection may be made using well-known techniques, such as ultrasonic or thermal welding (heat or laser) at the interface to form a seal (which is at least liquid-impervious and preferably hermetic). Alternatively, other means of connection (e.g., adhesives), may be used at the interface I, although this is obviously less preferred in view of the

desirability in most cases for the more reliable, leak-proof seal afforded using welding techniques. In either case, the judicious use of inert sealants may be made along the joint thus formed to ensure that a leak-proof, hermetic seal results. As discussed further below, the need for such an interface may be altogether eliminated by simply affixing the rigid portion 14 to an inside or outside surface of the bag 10 (see FIGS. 16a and 16b).

The bag 10 shown in FIG. 1 maybe manufactured as described above, with the fluid-agitating element 18 received on the post 20 (which may be accomplished using the techniques shown in FIGS. 1b and 1c). The empty bag 10 may then be sealed and folded for shipping, with the fluid-agitating element 18 held at the home location by the post 20. Holding in the axial direction (i.e., the vertical direction in FIG. 1) may be accomplished by folding the bag 10 over the post 20, or by providing the portion 20a that is oversized or very close in size to the opening 18a in the fluid-agitating element 18.

When ready for use, the bag 10 is then unfolded. It may then be placed in a rigid or semi-rigid support structure, such as a container C, partially open along at least one end such that at least the rigid portion 14 remains exposed (see FIG. 2). Fluid F may then be introduced into the bag 10, such as through an opening or fitting (which may be a sterile or aseptic fitting, in the case where the bag 10 is pre-sterilized or otherwise used in a sterile environment). As should be appreciated, in view of the flexible or non-rigid nature of the bag 10, it will generally occupy any adjacent space provided in an

adjacent support structure or container C when a fluid F (liquid or gas under pressure) is introduced therein (see FIG. 2).

An external motive device 24 is then used to cause the fluid-agitating element 18 (which is at least partially magnetic or ferromagnetic) to at least rotate to agitate any fluid F in the bag 10. In the embodiment of FIG. 2, the fluid-agitating element 18 is at least partially magnetic and is shown as being levitated by the motive device 24, which is optional but desirable. The levitation may be provided by a field-cooled, thermally isolated superconducting element SE (shown in phantom in FIG. 2) positioned within the motive device 24 and thermally linked to a cooling source (not shown). As also described therein, the fluid-agitating element 18 may then be rotated by rotating the superconducting element SE (in which case the fluid-agitating element 18 should produce an asymmetric magnetic field, such as by using at least two spaced magnets having alternating polarities). Another option is to use a separate drive structure (e.g., an electromagnetic coil) to form a coupling capable of transmitting torque to the particular fluid-agitating element (which may be "levitated" by a hydrodynamic bearing). While it is of course desirable to eliminate the need for a dynamic seal or opening in the bag through which a drive structure (such as a shaft) extends, the particular means used to levitate and/or rotate the fluid-agitating element 18 is not considered critical to practicing the inventions disclosed herein.

The fluid-agitating element 18 is also depicted as including a plurality of vanes or blades B to improve the degree of fluid agitation. If present, the vanes or blades B preferably project in a direction opposite the corresponding surface of the rigid portion

14. The particular number, type, and form of the vanes or blades B is not considered important, as long as the desired degree of fluid agitation for the particular application is provided. Indeed, in applications where only gentle agitation is required, such as to prevent damage to delicate suspensions or to merely prevent stagnation of the fluid F in the bag 10, the vanes or blades B need not be provided, as a rotating smooth-walled annular element 18 still provides some degree of agitation.

As explained above, it is important to not only know the general location or position of the fluid-agitating element 18 within the bag 10, but also to assure its position relative to the motive device 24. To do so, and in accordance with a second aspect of the invention, the rigid portion 14 maybe provided with a second receiver 26 to facilitate the correct positioning of the motive device 24 relative to the fluid-agitating element 18 when held at the home location. In the embodiment shown in FIGS. 1a and 1b, the second receiver 26 takes the form of a second post 28 projecting in a direction opposite the first post 20. Preferably, the second post 28 is essentially coaxial with the first post 20 (although the post 20 may be a separate component that fits into a receiver 14a defined by the second post 28; see FIG. 1c) and is adapted to receive an opening 24a, such as a bore, in the adjacent end face 24b forming a part of the housing for the motive device 24. Consequently, the second post 28 helps to assure that the alignment between the fluid-agitating element 18 (which is generally held in the vicinity of the first receiver 16/post 20, which is the home location) and the motive device 14 is proper such that the desired coupling for transmitting the levitation or rotational force may be formed.

Preferably, the second receiver 26, such as second post 28, has a cross-sectional shape corresponding to the shape of the opening 24a. For example, the second post 28 maybe square in cross-section for fitting in a correspondingly-shaped opening 24a or locator bore. Likewise, the second post 28 could have a triangular cross-sectional shape, in which case the opening 28 would be triangular. Myriad other shapes could also be used, as long as the shape of the second receiver 26 compliments that of the opening 24a such that it may be freely received therein. In this regard, it is noted that a system of matching receivers and openings may be used to ensure that the fluid-agitating element 18 in the bag 10 corresponds to a particular motive device 24. For example, in the case where the fluid-agitating element 18 includes a particular arrangement of magnets producing a magnetic field that corresponds to a particular superconducting element or drive structure, the second receiver 26 maybe provided with a certain shape that corresponds only to the opening 24 in the motive device 24 having that type of superconducting element or drive structure. A similar result could also be achieved using the relative sizes of the second receiver 26 and the opening 24a, as well as by making the size of the opening 18a in the fluid-agitating element 18 such that it only fits on a first receiver 16 having a smaller width or diameter, and then making the second receiver 26 correspond only to an opening 24a in a motive device 24 corresponding to that fluid-agitating element 18.

In many past arrangements where a rigid vessel is used with a fluid-agitating element directly supported by a bearing, an external structure is provided to which a motive device could be directly or indirectly attached and held in a suspended fashion.

This structure serves to automatically align the motive device with the fluid-agitating element supported therein. However, a bag 10 per se is generally incapable of providing reliable support for the motive device 24, which can weigh as much as twenty kilograms. Thus, the motive device 24 in the embodiments disclosed herein for use with a vessel in the form of a bag 10 is generally supported from a stable support structure (not shown), such as the floor, a wheeled, height adjustable platform, or the like. Since there is thus no direct attachment with the bag 10, the function performed by the second receiver 26 in aligning this device with the fluid-agitating element 18 is an important one.

Another embodiment of the vessel forming one aspect of the present invention is shown in FIGS. 3a and 3b. In this embodiment, the vessel is again a bag 10 including a flexible portion 12 and a rigid portion 14. The rigid portion 14 is cap or hat-shaped with a peripheral flange 22 for attachment to the flexible portion 12 of the bag 10. The connection between the two structures may be formed using the various techniques described above, and preferably results in a fluid-impervious, hermetic seal. The rigid portion 14 includes a first receiver 16 in the form of a recess or cavity 30 facing the interior of the bag (see action arrow B) for receiving a correspondingly-shaped portion of the fluid-agitating element 18 in the bag 10 and holding it at a home location, at least when oriented as shown in FIG. 3a. The portion of the fluid-agitating element 18 received in the cavity 30 is preferably the body 18b, which as described above is at least partially magnetic or ferromagnetic and may optionally support a plurality of vanes or blades B. Preferably, the body 18b of the fluid-agitating element 18 is circular in cross-section and the cavity 30 is sized and shaped such that the body (which need not

include opening 18a in view of the absence of post 20) may freely be inserted, rotate, and levitate therein. However, as with the first embodiment, the fluid-agitating element 18 could also be in the form of a conventional magnetic stirrer (which of course would not be levitated), such as a bar having a major dimension less than the corresponding dimension (e.g., the diameter) of the cavity 30. In any case, the fluid-agitating element 18 in this embodiment is again free of direct attachment from the first receiver 16, but is held at a home location, even in the event of accidental decoupling.

Thus, in the manner similar to that described above with respect to the first embodiment, the fluid-agitating element 18 may be positioned in the first receiver 16 in the bag 10. The bag 10 may then be sealed, folded for storage or shipping, stored or shipped, and ultimately unfolded for use. The folding is preferably completed such that the fluid-agitating element 18 is captured in the cavity 30 and remains held in place during shipping by an adjacent portion of the bag 10. Consequently, upon unfolding the bag 10, the fluid-agitating element 18 is at the expected or home location, but remains free of direct attachment and ready to be rotated (and possibly levitated). If levitated, the levitation height established by the superconducting bearing or hydrodynamic bearing is preferably such that at least a portion of the body 18b of the fluid-agitating element 18 remains within the confines of the cavity 30. This helps to assure that the fluid-agitating element 18 remains held at the home location (that is, in the vicinity of the first receiver 16), even in the case of accidental decoupling from the motive device 24. In other words, in the event of an accidental decoupling, the fluid-agitating element 18 will engage the sidewall of the cavity 30 and simply come to rest therein, which defines the

home location. This not only improves the chance of an automatic recoupling, but also makes the task of manually reforming the coupling an easy one.

An option to assure that a magnetic fluid-agitating element 18 remains associated with the first receiver 16, even if inverted, is to attach an attractive structure, such as a magnet 32 (shown in phantom in FIG. 3a), to the exterior of the rigid portion 14. The non-contact coupling thus established helps ensure that the fluid-agitating element 18 remains in the home location prior to being coupled to an external motive device. The magnet 32 is removed once the bag 10 is positioned on or in a support structure, such as a container C (see FIG. 2). Such a magnet 32 may also be used with the embodiment of FIG. 1, which eliminates the need for providing the post 20 with portion 20a. The magnet 32 is preferably annular with an opening that is received by the second receiver 26, which advantageously helps to ensure that the alignment is proper for forming the coupling.

Yet another option is to provide a frangible adhesive on the fluid-agitating element 18 to hold it in place temporarily in the first receiver 16 prior to use. The strength of any adhesive used is preferably such that the bond is easily broken when the fluid-agitating element 18 is levitated in the first receiver 16. Of course, the use of such an adhesive might not be possible in situations where strict regulations govern the purity of the fluid being mixed.

With reference to FIG. 3b, the first receiver 16 in this embodiment also serves the dual function of helping to align the fluid-agitating element 18 relative to an external motive device 24. Specifically, the periphery of the sidewall 34 and the end wall 36

defining the cavity 30 in the rigid portion 14 define a second receiver 26 adapted to receive an opening 24a formed in an adjacent face of a motive device 24. As described above, the opening 24a is preferably sized and shaped for being received by the second receiver 26, and may even help to ensure that the bag 10 is used only with a motive device 24 having the correct superconducting element or magnetic structure(s) for levitating and/or rotating the fluid-agitating element 18. For example, in the case where the sidewall 34 and end wall 36 provide the second receiver 26 with a generally cylindrical shape, the opening 24a is also cylindrical. Preferably, the opening 24a also has a depth such that the end wall 36 rests on the corresponding face 24c of the motive device 24. This feature may be important to ensure that the gap between the superconducting element and/or drive structure in the motive device 24 and the at least partially magnetic or ferromagnetic body 18b of the fluid-agitating element 18 is minimized, which helps to ensure that the strongest possible coupling is established and that the maximum amount of driving torque is transferred. The gaps are shown as being oversized in FIG. 3b merely to provide a clear depiction of the relative interaction of the structures shown. However, in the case where the entire housing of the motive device 24 is rotated, it may be desirable to provide a certain amount of spacing between the sidewall 34, the end wall 36, and the corresponding surfaces defining the opening 24a to avoid creating any interference.

FIGS. 4a and 4b show an embodiment similar in some respects to the one shown in FIGS. 3a and 3b. For example, the rigid portion 14 includes a peripheral flange 22 connected to the flexible portion 12 of the bag 10 to form a seal. Also, the rigid

portion 14 includes a sidewall 34 and end wall 26 that together define a cavity 30. However, a major difference is that the cavity 30 of the rigid portion 14 essentially faces outwardly, or toward the exterior of the bag 10 (e.g., in a direction opposite action arrow B). Consequently, the sidewall 34 and end wall 36 define the first receiver 16 for receiving the fluid-agitating element 18, which is shown having an annular body 18b that is at least partially magnetic or ferromagnetic and may support a plurality of vanes or blades B. As should be appreciated, the first receiver 16 in the form of the periphery of the sidewall 34 provides a similar receiving function as both the post 20 and the cavity 30 of the other embodiments, since it is capable of maintaining, holding, or confining the fluid-agitating element 18 substantially in a home or expected position within the bag 10. The maximum amount of side-to-side movement is of course dependent on the size of the opening 18a in the fluid-agitating element.

Additionally, the outwardly-facing cavity 30 is adapted to serve as the second receiver 26 for receiving a portion of a motive device 24 used to levitate and rotate the fluid-agitating element 18 and serving to align the two. Specifically, the motive device 24 may include a head end 24d adapted for insertion in the cavity 30 to form the desired coupling with the fluid-agitating element 18 positioned adjacent thereto. As with the embodiments described above, the spacing between the head end 24d and at least the sidewall 34 is preferably minimized to maximize the strength of the coupling between the motive device 24 and the fluid-agitating element 18. Moreover, in view of the rigid nature of the rigid portion 14, the end face 24b of the head end 24d may rest against

and assist in supporting the bag 10 (which, as described above, maybe positioned in a separate, semi-rigid container (not shown)).

In each of the above-referenced embodiments, the possible use of a levitating fluid-agitating element 18 with a superconducting bearing or a hydrodynamic bearing is described. In such systems, a real possibility exists that the fluid-agitating element 18 might accidentally decouple or disconnect from the motive device 24, such as if the fluid is viscous or the amount of torque transmitted exceeds the strength of the coupling. In a conventional bag, the process of reestablishing the coupling is extraordinarily difficult, since the location of the fluid-agitating element 18 within the bag 10 is unknown. In a sterile environment, opening the bag 10 and using an implement to reposition or "fish" out the fluid-agitating element 18 is simply not an option. Thus, an added advantage of the use of the first receiver 16 in each of the above-referenced embodiments is that, despite being free from direct attachment, it still serves the function of holding the fluid-agitating element 18 at the home location in instances where accidental decoupling occurs. This significantly reduces the downtime associated with such an event, since the general position of the fluid-agitating element 18 is known. The use of a first receiver in the bag 10 also improves the chances of automatic recoupling, since the fluid-agitating element 18 remains generally centered relative to the motive device 14 and held generally at the home location, even when decoupling occurs.

A related advantage is provided by forming the first receiver 16 in or on a rigid portion 14 of the bag 10. Specifically, in the case where a fluid-agitating element rests on a surface of a bag, the contact over time could result in damage and could even lead

to an accidental perforation, which is deleterious for obvious reasons. The possibility for such damage or perforation also exists when a levitating fluid-agitating element 18 accidentally decouples. Advantageously, the potential for such damage or perforation is substantially eliminated in the foregoing embodiments, since the first receiver 16 helps to keep the fluid-agitating element 18 adjacent to the flange 22 of the rigid portion 14, which is generally thicker and less susceptible to being damaged or perforated. In other words, if the fluid-agitating element 18 becomes decoupled, it only engages or contacts the rigid portion 14 of the bag 10. Thus, it is preferable for the flange 22 to be oversized relative to the fluid-agitating element 18.

While the embodiments of FIGS. 1-4 are described as bags 10 including both a flexible portion 12 and a rigid portion 14, it should be appreciated that the present invention extends to a completely rigid vessel (that is, one made of metal, glass, rigid plastics, or the like). In the case of a rigid vessel, the post 20 preferably includes a portion 20a for capturing the fluid-agitating element 18 thereon, but without any other means of direct attachment or bearing.

Up to this point, the focus has been on a fluid-agitating element 18 capable of levitating in the vessel. However, as briefly noted above, the inventions described herein may also be applied to a bag 10 in combination with a fluid-agitating element 18 directly supported by one or more bearings. For example, as shown in FIGS. 5a and 5b, the first receiver 16 associated with the rigid portion 14 of the bag 10 may be in the form of an inwardly-projecting post 20 including a slide bearing 40 for providing direct support for the fluid-agitating element 18. The bearing 40 is preferably sized and shaped such

that it fits into an opening 18a forming in the fluid-agitating element 18, which may rest on the adjacent surface of the post 20 or may be elevated slightly above it. In either case, it should be appreciated that the first receiver 16 receives and holds the fluid-agitating element 18 in a home location, both during shipping and later use.

In view of the direct nature of the support, the material forming the slide bearing 40 is preferably highly wear-resistant with good tribological characteristics. The use of a slide bearing 40 is preferred in applications where the bag 10 is disposable and is merely discarded, since it is less expensive than a corresponding type of mechanical roller bearing (and is actually preferred even in the case where the bag 10 is reused, since it is easier to clean). However, it is within the broadest aspects of the invention to provide the first receiver 16 with a conventional roller bearing for providing direct, low-friction, rolling support for the rotating fluid-agitating element 18, although this increases the manufacturing expense and may not be acceptable in certain applications.

The rigid portion 14 of the bag 10 in this embodiment may further include a second receiver 26 in the form of a second post 28 coextensive and coaxial with the first post 20. The second post 28 is received in an opening 24a formed in an end face 24b of a motive device 24. In view of the direct support provided for the fluid-agitating element 18 by the bearing 40, the motive device 24 in this case includes only a drive structure DS (shown in phantom in FIG. 5b) for forming a coupling with the body 18b, which is magnetic or ferromagnetic (iron, magnetic steel, etc.). The drive structure DS may be a permanent magnet or may be ferromagnetic, as necessary for forming the coupling with the fluid-agitating element 18, which may be disc-shaped, cross-shaped, an elongated

bar, or have any other suitable shape. The drive structure DS may be rotated by a direct connection with a motor (not shown), such as a variable speed electric motor, to induce rotation in the fluid-agitating element 18. Alternatively, the drive structure DS may be an electromagnet with windings to which current is supplied to cause the magnetic fluid-agitating element 18 rotate and possibly levitate slightly to create a hydrodynamic bearing.

FIGS. 6a and 6b show an embodiment of the bag 10 in which the first receiver 16 is in the form of a cavity 30 formed in the rigid portion 14 and facing inwardly. A bearing 40 is provided in the cavity 30 for providing direct support for a fluid-agitating element 18 positioned therein. As with the embodiment described immediately above, the bearing 40 may be a slide bearing adapted for insertion in the opening 18a of the fluid-agitating element 18 formed on the head end of a post 42. The post 42 may be supported by or unitarily formed with the end wall 36. Despite the depiction of a slide bearing 40, it is reiterated that the particular type of bearing used is not considered critical, as long as rotational support is provided for the fluid-agitating element 18 and the other needs of the particular fluid-agitating operation are met (e.g., low friction, reduced expense, easy clean-up, etc.).

The body 18b of the fluid-agitating element 18, which is at least partially magnetic or ferromagnetic, is sized to fit within the sidewall 34 defining the cavity 30 and, thus, is capable of rotating therein as the result of an externally-applied, non-contact motive force. The periphery of the sidewall 34 also defines a second receiver 26 for receiving a corresponding opening 24a in a motive device 24, which in view of the

direct support provided by bearing 40 need only provide the force necessary to rotate the fluid-agitating element 18 in a non-contact fashion.

As should be appreciated, the embodiment shown in FIGS. 7a and 7b is the direct support counterpart for the embodiment shown in FIGS. 4a and 4b. The rigid portion 14 again includes a cavity 30 facing outwardly or toward the exterior of the bag 10 and a first receiver 16 for receiving and defining a home location for a fluid-agitating element 18. The first receiver 16 includes a bearing 40 for supporting the fluid-agitating element 18, which again is at least partially magnetic or ferromagnetic. The bearing 40 may be a slide bearing formed on the head end of a post 44 integral with the end wall 36 of the rigid portion 14 and adapted for fitting into an opening or recess 18a in the fluid-agitating element 18, or may be a different type of bearing for providing support therefor.

The motive device 24 includes a head end 24d adapted for insertion in a second receiver 26 defined by the cavity 30. This head end 24d preferably includes the drive structure DS that provides the force for causing the at least partially magnetic or ferromagnetic fluid-agitating element 18 to rotate about bearing 40. In FIGS. 7a and 7b, it is noted that the fluid-agitating element 18 includes an optional depending portion 18b that extends over the sidewall 34. As should be appreciated, this portion may also be magnetized or ferromagnetic such that a coupling is formed with the drive structure DS. A similar type of fluid-agitating element 18 could also be used in the levitation scheme of FIGS. 4a and 4b.

FIG. 1

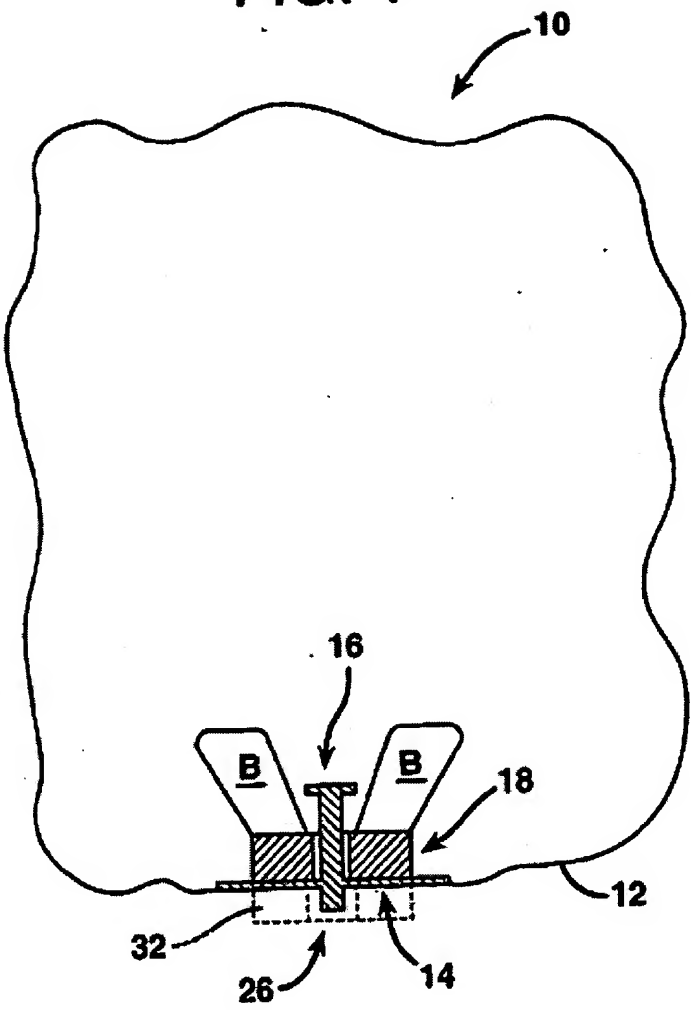


FIG. 2

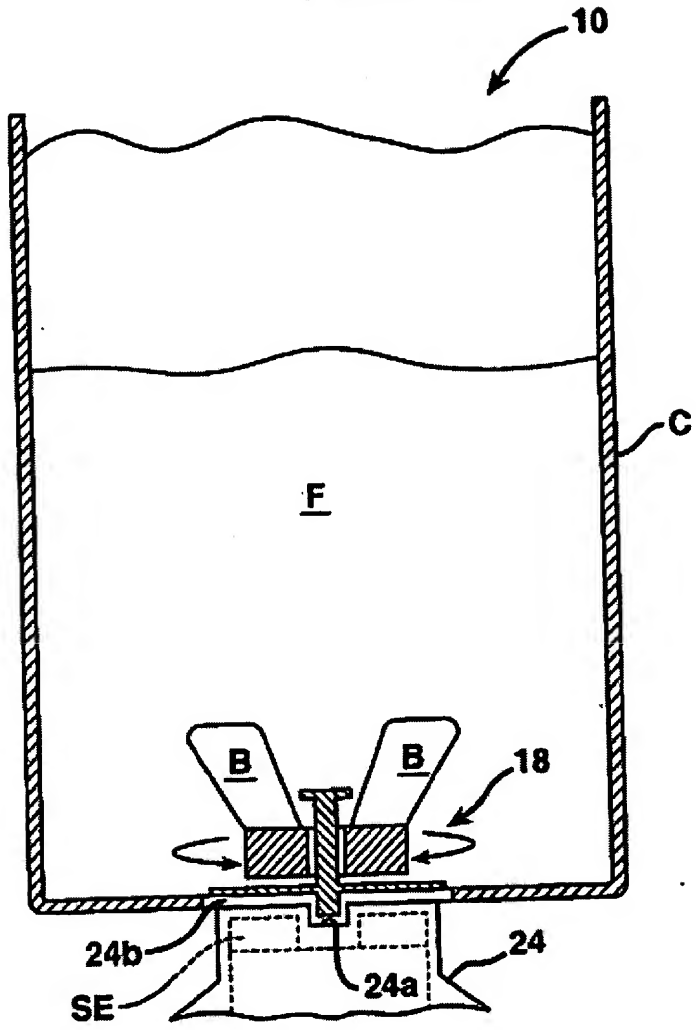


FIG. 3A

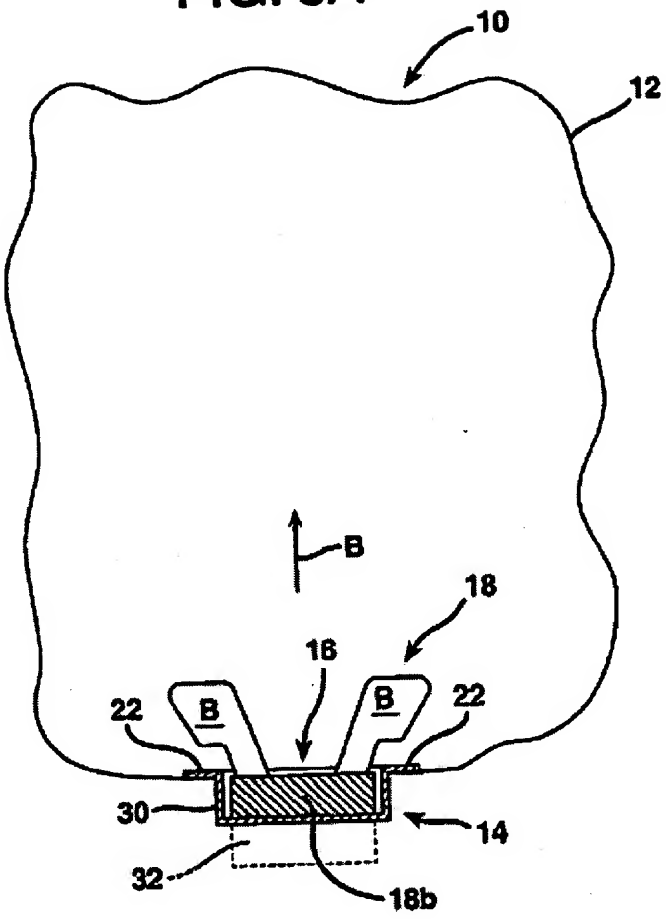


FIG. 3B

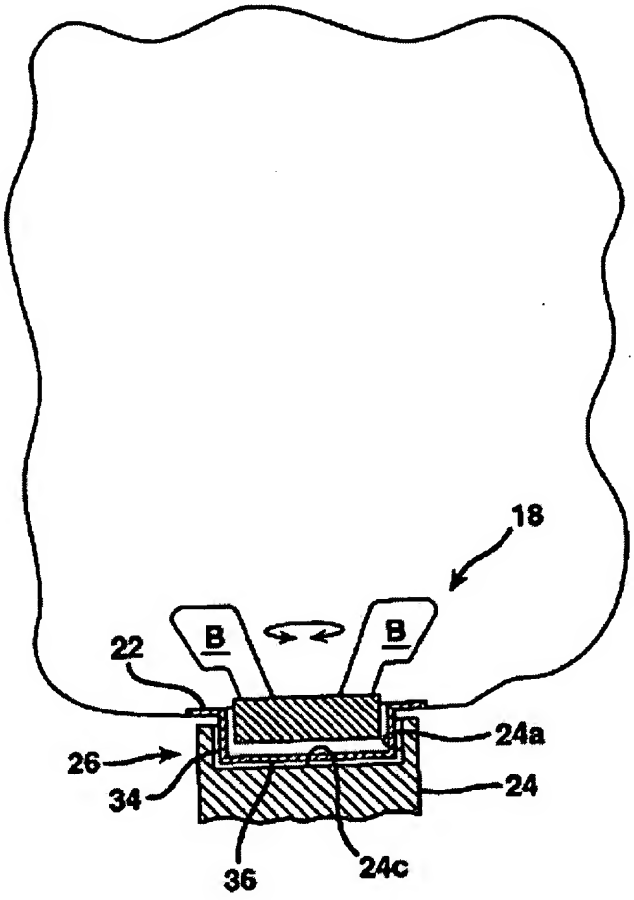


FIG. 6A

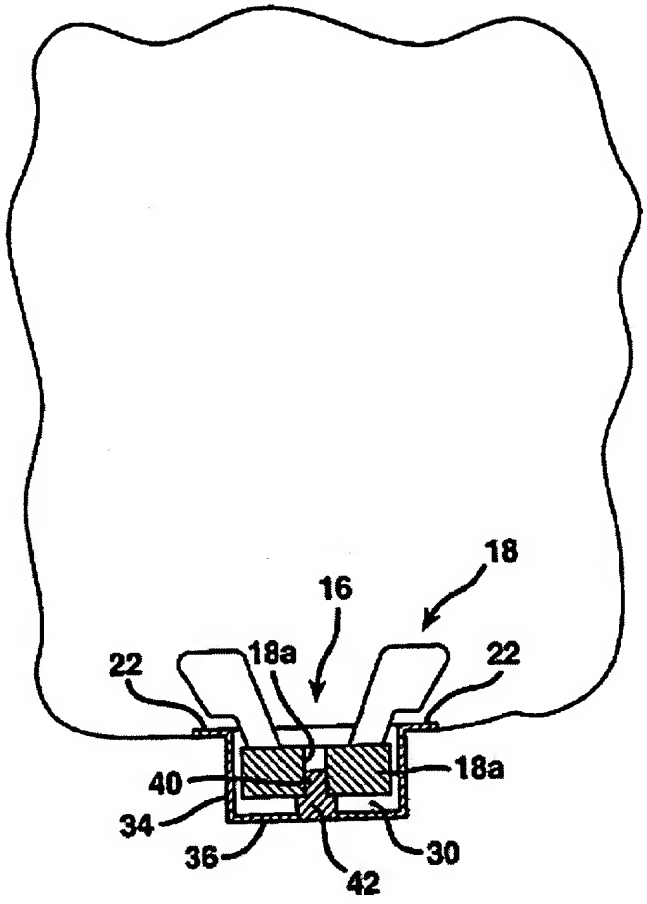
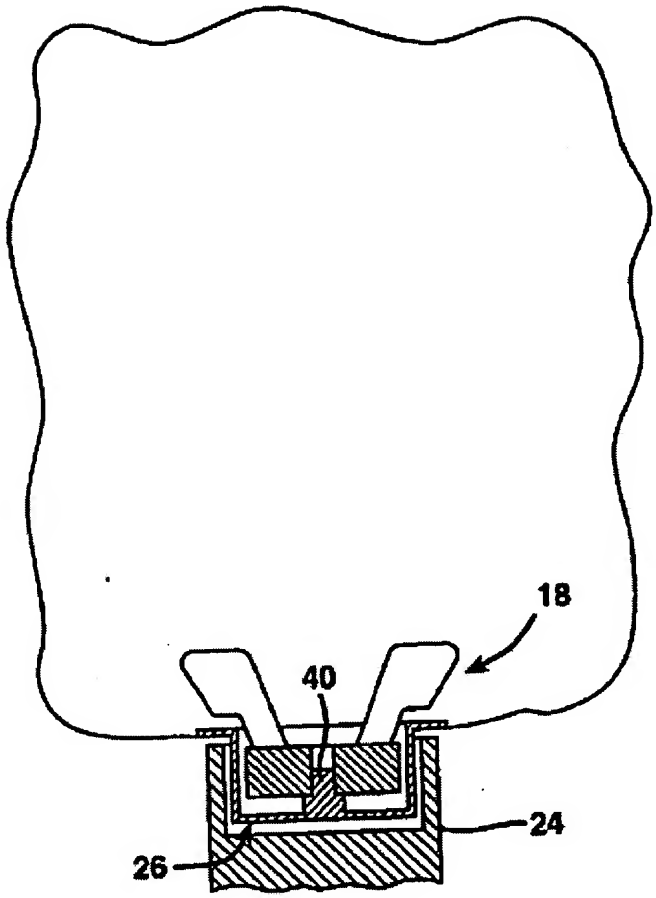


FIG. 6B



Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 3 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terentiev (US 2005/0002274) in view of Vallot (US 5,988,422).

Terentiev (US 2005/0002274) does not disclose recited panels or layers of the bag body. The patent to Vallot discloses a bag body for fluids including multiple polymeric panels or layers 20-23 seamed together. It would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have provided the bag body of Terentiev (US 2005/0002274) with multiple panels or layer

seamed together as taught by Vallot for the purpose of imparting strength to the bag to facilitate transportation thereof without rupture (see col. 1, line 13 through col. 2, line 62 and col. 6, lines 60-67).

16. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Terentiev (US 2005/0002274) in view of Coleman (US 3,647,397).

Terentiev (US 2005/0002274) does not disclose the recited lid. The patent to Coleman Vallot discloses a bag body 2 with a magnetic stirrer 2 therein; the bag body 2 placed in an outer container 30; the container having al id 32. It would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have provided the container of Terentiev (US 2005/0002274) with a lid as disclosed by Coleman for the purpose of closing the container and maintain sterility of the contents of the bag (col. 3, lines 25-45).

Allowable Subject Matter

17. Claims 5, 6, 17-20, 25-27, 31, 35, 38, and 43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

18. The following is an Examiner's statement of reasons for the indication of allowable subject matter:

The prior art of record does not teach or fairly suggest the retention cover with opening(s) or the details of the outer container.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The cited prior art discloses magnetic stirring devices and methods.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles E. Cooley whose telephone number is (571) 272-1139. The examiner can normally be reached on Mon-Fri. All official facsimiles should be transmitted to the centralized fax receiving number 571-273-8300.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles E. Cooley
Primary Examiner
Art Unit 1723

5 December 2005